IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
STATESVILLE DIVISION

RAMONA WINEBARGER and REX WINEBARGER,
Plaintiffs,

CASE NOS. 5:15CV57-RLV; 3:15CV211-RLV

v.
BOSTON SCIENTIFIC CORPORATION,
Defendant

MARTHA CARLSON,
Plaintiff,

v.

BOSTON SCIENTIFIC CORPORATION
Defendants

PLAINTIFFS OBJECTIONS AND COUNTER DESIGNATIONS TO DEFENDANT BOSTON SCIENTIFIC'S DEPOSITION DESIGNATIONS OF DENNIS MILLER, M.D. TAKEN ON NOVEMBER 15, 2013

BSC Designations	Objection	Plaintiffs Counter Designation
dm052314, (Pages 465:17 to 477:2) 465 17 What are the surgical treatment 18 options that -- for pelvic organ prolapse? 19 A Well, this is a very important aspect to all of our 20 discussion because we treat prolapse in a variety of 21 ways. For myself, I use all three of these methods 22 to treat prolapse, and it's all about patient 23 selection and who the patient is and who you are as a 24 surgeon. 466 1 And so the first approach is the 2 so-called native tissue repair, which is the anterior 3 and posterior repair, which is lifting of the vaginal 4 tissues. It's been around since about 1917, with 5 suspension of the vagina. And generally, if the	465:17-477:2 FRE 401, 402, 403 701, 702 Dr. Miller is not designated as an expert.	

woman has a uterus, it involves performing a hysterectomy as well. Q And are there limitations to that type of surgery in terms of drawbacks? A Yeah. Every textbook in OB/GYN dating back even into the '50s has referred to the unfortunate degree of failure. You know, when you talk to women who are older, they'll tell you that their physicians told them that the repairs would only last five years. And they'll be familiar, "Oh, yes, my mother had that done two, three, four times." And so one of the main limitations of the native tissue repair that mean we can't use it in every single patient is that there's substantial failure. And the other aspect to it is, you know, there's a lot of suture entrapment issues, and there's binding that happens. In some studies the painful intercourse rates are 50 percent of the 467 patients. And so there's -- there is limitations to any surgery, of course. And I performed native tissue repair in a substantial portion of my patients, but those are the limitations to it. Q And then the second bullet point is abdominal colposacropexy. Tell the jury what that is. A It's important to suspend the vagina at its deepest part. That's -- that's really the -- the center tent pole of your tent. And the colposacropexy is an attempt to fixate the vagina inside the abdomen going from above. The problem is the vagina won't reach the fixation point, so you generally have to add -- as a part of this operation, you always have to add a graft material of some type. Polypropylene is currently considered the best, and so it is the most		

common graft used. So polypropylene mesh is generally used to suspend the vagina. But, again, you have to move the colon, you have to move the rectum and the bladder, and you have to expose the sacrum in order to fixate this piece of mesh from the vagina to the sacrum. Q So how does abdominal -- abdominal sacrocolpopexy 468 differ from transvaginal mesh in bullet point 3? What's the difference between those two? A The difference is the approach. Mesh is placed generally laparoscopically or robotically from above after the performance of a hysterectomy, versus the transvaginal mesh is taking that same polypropylene mesh and inserting it transvaginally. Q And are there other limitations or drawbacks that you have to consider before performing an abdominal sacrocolpopexy? A Well, it's a good surgery as well, as is native tissue repair. That's why I perform all three. But the limitations are, for one thing, the complexity of the operation; the very act of having to move the colon and the rectum and the bladder. And there's a 1 percent incidence of bowel obstruction because the mesh is inside of the abdomen. Q And then the third bullet that you identify on the surgical options says "Transvaginal" -- "Transvaginal (vaginal mesh)." Tell the jury what that means. A Well, that means taking that same polypropylene mesh 469 or -- you know, in -- other grafts can be used, biological grafts can be used, but taking a graft, generally polypropylene, and fixing it from a transvaginal approach.		

So you don't need to move those other organs in order to get to the place where you want to fixate -- where you want to fixate the mesh. So it's another one of the options for doing it.

Q And both the abdominal sacrocolpopexy and the transvaginal mesh involve using a graft or a mesh material of some kind?

A Yes.

Q And what's the purpose of that? What function does the mesh itself provide? Why is it used in those surgeries?

A Well, the goal -- the goal of it is to attempt to increase the durability of that repair because, you know, what we've -- what we've known for many years, and I've seen in my own practice even, is that you -- you can't expect all these repairs to -- to last over time.

And the -- the introduction of mesh is about improving the durability of the repair.

Q Has -- transvaginal mesh, has it gone through

developments over time?

A Yes. Transvaginal mesh has been around, as I said, since the 1980s. And I first saw it when performed by Dr. Tom Julian in Madison, who was one of the early proponents and one of the early investigators to publish on it.

And for many years we would cut our mesh and fixate it with suture or with the Capio device. There are a variety of ways of putting them -- putting the mesh in place.

But one of the challenges in doing it -- and this is where the devices came in -- is you're trying to perform surgery through what is essentially a very small opening. The vaginal opening -- to enter through the vaginal opening

is difficult, particularly because the most important part of the repair is something that's 5 or 6 inches away deep inside.

And so that's where the evolution came in, how can we have a more effective fixation? How can we do a better job of providing a way to deliver the mesh into the play -- into where we want it to be?

Q I want to flesh this out a little bit more.

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If you could turn over to slide 19 and explain to the jury what this demonstrates in terms of the evolution of vaginal mesh.

A When you look at the top left, the mesh sheets, that's -- that's how mesh came. And so mesh was then introduced in a variety of ways.

And by 2000, surgeons began to -- beginning in Australia and Italy and France and the U.S., particularly Tom Julian, began to customize those shapes.

But if you look at them, they were all sort of irregular, and there was a lack of reproducibility. And so there was this very inconsistent way of fixing the mesh into place and inconsistent shapes to the mesh going through what is this difficult opening.

And then on the bottom --

Q So before we go to the bottom, so on the top when we -- these sheets of mesh, the square sheets, and then in the middle of the page the one that's cut to shape, are these polypropylene sheets of mesh?

A Yes. The ones you see here are polypropylene.

Q And so was polypropylene mesh being used to treat pelvic organ prolapse back in -- back this far?

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A You know, my practice goes back to 1989, and so it's hard for me to comment about prior to 1989. But yes, certainly throughout my entire career I've been aware of surgeons using grafts, and particularly polypropylene, to reinforce their repairs. Q And then take the jury, then, from the first two -- the top, the three pictures on the top, to the bottom. What's the advancement that was made, then, after 2004 when we start talking about first-generation kits? A Well, surgeons in general started to talk together about ways of improving the ability to fixate the mesh, to deliver it. And we started talking about, you know, we know where we want it to go and we know what we want to do; we want to fix it. But just how do you do it? We need a new hammer; we need a new screwdriver. And industry became involved with their engineers at creating fixation devices. And the first generation was to use -- can I grab this? Q Sure. A -- to use these trocars and to pass them through the 473 skin and through the buttock area and just lateral to the vagina and have it enter the vagina at its topmost place. And that really improved substantially our ability to get mesh into place. But, you know, we're -- we're always trying to move forward. And one of my thoughts was, Can we do this without passing these trocars? And so could we fixate the mesh by going in through the same		

incision and yet still reach that area 5 or 6 inches away? Q So the -- what is the device that you're holding in your hand? A This is a needle that is from a Prolift device. Q Okay. And that was part of a device that came on the market prior to the Pinnacle and Uphold devices? A That is correct. (Exhibit 1038 marked for identification.) BY MR. ANIELAK: Q I've marked as Deposition Exhibit No. 1038 a presentation that has your name on the outside of it. Do you see that? A Yes. Q And this was a presentation that you made in 2007? A Yes. 474 Q And I want to talk about a couple of your slides in here to flesh out this discussion regarding the medical devices that were on the market prior to the Pinnacle device, okay? If you turn over to slide 4, which is 658. So in terms of the history of the development of medical devices that treat pelvic organ prolapse, tell the jury what these devices are. A Apogee/Perigee was the first device to market; Prolift second; and Avaulta third, which are fixation devices to improve the way that we get the mesh to the desired fixation spots and to secure it down. And so they're just examples of using those needles. All relatively similar needle techniques to introduce the mesh. Q And did these devices use polypropylene mesh? A Yes. Q If you turn over to the next slide. And what -- what are you conveying here when you're talking about the current lift kit		

advantages? And before you get into more detail, you're talking about the devices that were on the market prior to Pinnacle; is that right? 475 A Apogee/Perigee, Prolift, and Avaulta. Q And what were some of their advantages? A Well, for years, surgeons had been introducing mesh with no real reproducibility and with a variety of different fixation devices. The so-called lift kits provided a way to reproducibly get the mesh into place, and it provided an amount of adjustability because of the wings that you don't have when you just sew it into place; you're locked into the location where you sew it in. And it avoids sutures which encircle the tissues and can compress the tissues and cause ischemia. And the suture -- the suture fixation of the sacrospinous ligament is associated with 6 percent incidence of buttock pain. And so it allows you to avoid those sutures and allows you to easily get to the location you wanted to get to. Q When you turn to the next page, you discuss some of the limitations of the devices that were on the market prior to Pinnacle; is that right? A Yes. Q And what were some of those limitations of the medical devices that were on the market to treat 476 prolapse prior to Pinnacle? A Well, they were good -- they were good devices, and they were being used safely. I had good experience with them. But it did strike me that you're passing these needles through anatomy that you can't see and		

in proximity to neurovascular structures. And so I saw the advantage of being able to introduce the mesh directly through the vaginal incision. Q So tell the jury why passing the needles through unfamiliar anatomy, why is that a bad thing? A Well, it's not a bad thing. Q Okay. Tell the jury what the limitation is of that technique. A In medicine, less is more, and you always want to move forward to increasing simplicity. And passing these needles adds another step going through tissues that have nerves and blood vessels in them. And while -- while that's a path that we are generally good at doing, if I can do it directly through the incision, I'm going to -- I'm going to want to do that. Q Okay. What's the advantage of doing it directly through the incision as the Pinnacle device does? A I'm not passing through those structures. I'm 477 bypassing them. I can directly visualize the structure I want to fixate to.		
dm052314, (Pages 491:16 to 492:9) 491 Q And in terms of your overall experience with the Pinnacle device in terms of it successfully treating pelvic organ prolapse, what has been your experience? A You know, I've now had five years of experience with the device. And I see all of my patients back, and then over time, you see less of them. And we have had only the expected amount of complications that you get with any surgical procedure and had really 492 good outcomes with really satisfied patients by and	491:16-492:9 FRE 401; 403; 701; 702 Dr. Miller is not designated as an expert.	

large. Q In terms of successfully treating pelvic organ prolapse over the time that you've seen your patients over the last four or five years, have you been pleased with the outcomes in terms of treating their prolapse? A I have been. I have been happy with the results that I've seen going out even to five years after surgery.		
dm052314, (Pages 493:13 to 497:16) 493 Q Okay. In terms of -- Pinnacle went on the market in January of 2008. When did you start performing Pinnacle surgeries in terms of when Pinnacle went on the market? A I performed the first Pinnacle procedure. Q And so was that pretty soon after January of 2008? A It was during January of 2008. Q And you were asked some questions earlier about clinical trials. Were there any clinical trials specifically with Pinnacle prior to going to market 494 in January of 2008? A No, there were not. Q Why were you comfortable using Pinnacle in January of 2008 in patients when there weren't clinical trials specifically with the device? A Because it's one of the important concepts that is sometimes lost in this debate, and that is what I have invented is an incremental improvement in the way we tack mesh down. It's a new hammer; it's a new screwdriver. Mesh and grafts in general have been used for many, many years to treat prolapse, and	493:13-497:16 FRE 401; 403; 701; 702 Dr. Miller is not designated as an expert.	

there have been incremental changes throughout all of that time period. There's been vast amounts of research. In fact, there's far more research for the vaginal approaches to mesh than the abdominal approaches to mesh and, frankly, to the native tissue repair approaches to mesh -- to prolapse repair.

And so we -- in my mind and what I decided for my patients was that this was an incremental change in my tools. And surgeons change their tools all the time.

The procedure is mesh-reinforced prolapse repair, and the tools you use will evolve

over time.

Q. Had -- mesh-enforced prolapse repair, had that been done prior to Pinnacle coming on the market?

A. Yes. Mesh-reinforced prolapse repair has been a part of the armamentarium of urogynecologists for many years.

Q. And has that also been true of polypropylene mesh-based prolapse repairs?

A. Yes. Polypropylene has been, over the decade and beyond -- the last decade and beyond, the most commonly used graft.

Q. You mentioned to the jury earlier that you use different techniques in treating pelvic organ prolapse; some native tissue, some abdominal sacrocolpopexy, and then some transvaginal mesh. Is that right?

A. Yes.

Q. What is the benefit of having those different options in terms of treating your patients?

A. It's critical. It's critical because not every patient has the same need.

And every surgeon, just like every orthopedist and every back surgeon, every heart surgeon, we have to make determinations about what's

best for this patient, is -- based on who that patient is and what her anatomy is like, as well, and what her wishes are.

Because that's another piece that's forgotten in all of this, is that these patients -- that's one of the reasons that led me to eventually write a paper on informed consent, is a lot of this is -- you know, patients come in, and they'll tell you what their goals are.

And a lot of patients, their goal is "Look, my friend, my sister, my mother has had three failures of the surgery, so one thing I'm looking for is a durable procedure. What can you do to give me a durable procedure?"

Or in my practice, many of the patients have already had failures of their prior surgeries, and they're coming to me with that in mind.

Now, that's not true for everybody. Some patients come with entirely different requests.

And so it's really this joint decision, and you can only have that joint decision if you have multiple ways to fix prolapse.

So every patient sees essentially that

slide that you had on the three different approaches, and every patient I go through what are inevitably the pros and the cons.

You can't ever set this up as if there would be no cons to an approach because there's cons to every surgery. It's why, in my own personal life, I try to avoid surgery if I can. And whether that's having a plate put in or a screw put in or having a native tissue hernia repair, whatever your surgery is, there are potential complications and there are potential failures and you balance that out.

12 And every surgeon and every patient 13 makes that decision individually in this joint 14 process. Informed consent is a process. It's not a 15 document. It's not a piece of paper to be signed. 16 It's this process that you go through.		
dm052314, (Pages 498:23 to 499:18) 498 23 Q You were asked some questions about polypropylene, 24 the material that's used both in the Pinnacle device 499 1 in midurethral slings and in the Uphold device. 2 When Pinnacle came to market and 3 today, are you comfortable with polypropylene as the 4 material that's used to make those meshes? 5 A I'm comfortable with it based on the fact that there 6 has been volumes of literature and a large world 7 literature review of all the studies that have 8 been published. 9 And I've had long experience with it, 10 and I -- you know, back in the beginning, I 11 trusted Dr. Julian's long experience with it that 12 came before my long experience with it. 13 And as I saw my patients back, I 14 became increasingly more comfortable with it. And as 15 other surgeons were adopting it and continuing to 16 perform mesh-reinforced prolapse repairs and they 17 found that utilizing this fixation device helped them 18 accomplish it, that increased my confidence in it.	498:23-499:18 FRE 401; 403; 701; 702 Dr. Miller is not designated as an expert.	*[Counter Designation to 498:23-499:18]* *dm052314, (Pages 568:23 to 569:4)* *568* *23 Q This is -- this is the transcript -- if you'll look* *24 at the screen just real briefly, this is the* *569* *1 transcript from the webinar of February 25th, which* *2 has previously been marked as Exhibit 775 to your* *3 deposition, correct?* *4 A Yes.* *dm052314, (Pages 569:24 to 570:3)* *569* *24 You were the innovator of the* *570* *1 Pinnacle, and then you and Dr. Goldberg share the* *2 royalties on Uphold, true?* *3 A True.* *dm052314, (Page 570:8 to 570:21)* *570* *8 Q And what you say here is you do both Upholds* *9 and Pinnacle. But four out of five for anterior* *10 pelvic organ repair you use the Pinnacle. True?* *11 A Yes.*

		12 Q "Because I feel like if you have a small piece of *13 mesh, you run the risk of shrinkage causing too much* *14 tension."* *15 Did I read that correctly?* *16 A Correct.* *17 Q "And I do feel that with the Uphold you have to be* *18 even more cautious about not overtensioning because* *19 you don't have that margin of error to accommodate* *20 for the shrinkage that occurs"; is that correct?* *21 A Yes.* *571* *7 Q You would still today, sitting here in May 2014,* *8 agree that there is shrinkage that occurs when the* *9 body has polypropylene mesh implanted for pelvic* *10 organ prolapse repair?* *11 MR. ANIELAK: Form.* *12 THE WITNESS: I believe that in -- and this* *13 is an important distinction. I believe that in all* *14 prolapse surgery, whether sutures or grafts are used,* *15 shrinkage is an issue.* *16 We deal with vaginal stenosis and* *17 native tissue repairs and we deal with the shrinkage* *18 that occurs when you operate. We have to take into* *19 account shrinkage of the vagina anytime we operate on* *20 it, including with these products.* *21 And I -- and I felt particularly at* *22 that time that -- that Pinnacle had a -- had a -- had*

		23 a tolerance to shrinkage that I liked. dm052314, (Pages 572:12 to 573:7) *572* *12 Q But there is an experience of shrinkage around the* *13 polypropylene implant, correct?* *14 MR. ANIELAK: Form.* *15 THE WITNESS: Yes.* *16 BY MR. PERDUE:* *17 Q Your point here in comparing Pinnacle, which has a* *18 bigger piece of mesh, as opposed to Uphold, which has* *19 a smaller piece of mesh, is that there is a margin* *20 for error to account for the shrinkage that is better* *21 achieved in Pinnacle?* *22 MR. ANIELAK: Form.* *23 THE WITNESS: That's what I was speculating* *24 about at that time.* *573* *1 BY MR. PERDUE:* *2 Q That was -- that's your opinion as of February 2010?* *3 MR. ANIELAK: Form.* *4 THE WITNESS: It was my opinion in 2010,* *5 that you have to be cautious about overtensioning* *6 because shrinkage is one of the things that we deal* *7 with in surgery, yes.* *dm052314, (Pages 574:23 to 575:17)* *574* *23 Q You, Dr. Miller, understood, as a physician who is*

		24 involved in stress urinary incontinence and pelvic *575* *1 organ prolapse surgery, that women who would undergo* *2 transvaginal repairs that involve the use of* *3 polypropylene -- polypropylene mesh could suffer* *4 shrinkage around the mesh implant after surgery?* *5 MR. ANIELAK: Form.* *6 THE WITNESS: You can't say "suffer" -- you* *7 can't suffer shrinkage.* *8 BY MR. PERDUE:* *9 Q Would experience. Would experience shrinkage around* *10 the implant, fair?* *11 MR. ANIELAK: Form.* *12 THE WITNESS: Connective tissue that is* *13 operated on shrinks. Every scar you have shrinks,* *14 including, but not limited to, those repairs that* *15 include polypropylene. Even though there's data that* *16 says otherwise, that is what I believe.* *dm052314, (Page 578:14 to 578:16)* *578* *14 Q Tissues shrink when operated on, and tissues exposed* *15 to polypropylene mesh shrink around it, fair?* *16 A Yes*

1. **Objections to Designated Exhibits.**

    a. Plaintiffs object to Miller 1037 under FRE 401, 402, and 403 as the overview post-dates implantation of the Uphold devices at issue. Additionally, this exhibit impermissibly injects FDA testimony into the case.

2. **Plaintiffs Counter Exhibits**

    a. Miller 775

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on June 26, 2015, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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